IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

MANNATECH, INC.	§	
	§	
Plaintiff,	§	
	§	
VS.	§	NO. 3-06-CV-0813-P
	§	
TECHMEDICA HEALTH, INC., ET AL.	§	
	§	
	§	
Defendant.	§	

FINDINGS AND RECOMMENDATION OF THE UNITED STATES MAGISTRATE JUDGE

In this patent case, plaintiff and defendants seek construction of certain disputed claim terms. Having considered the claim language, the patent specification, the prosecution history, and the other evidence and briefing submitted by the parties, the magistrate judge issues the following claim construction recommendation:

I.

Plaintiff Mannatech, Inc. is the owner by assignment of four patents for glyconutritional dietary supplements--U.S. Patent No. 6,929,807 ("the '807 Patent"), U.S. Patent No. 7,157,431 ("the '431 Patent"), U.S. Patent No. 7,196,064 ("the '064 Patent"), and U.S. Patent No. 7,202,220 ("the '220 Patent"). The '807 Patent, entitled "Compositions of Plant Carbohydrates as Dietary Supplements," claims a dietary supplement composition of nutritionally effective amounts of isolated and purified saccharides for the promotion and maintenance of good health. (*See* Plf. Cl. Constr. App. at 4). The other patents are continuations of and share a common specification with the '807 Patent. (*Compare id.* at 4-18 *with id.* at 20-34, 36-50, & 52-67). In this lawsuit, plaintiff alleges that

certain dietary supplements manufactured and sold by defendants under the brand names Nutratose® and Activive® infringe one or more claims of the '807, '431, '064, and '220 Patents. (*See* Plf. Sec. Am. Compl. at 3, ¶ 12, 4-5 ¶¶ 17-31, & 6, ¶¶ 37-41).[1] Defendants deny any infringement and maintain that the patents-in-suit are invalid for a variety of reasons.

II.

The threshold issue in any patent infringement case is claim construction. "A claim in a patent provides the metes and bounds of the right which the patent confers on the patentee to exclude others from making, using, or selling the protected invention." *Corning Glass Works v. Sumitomo Electric U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989). Claim construction is a question of law for the court to decide. *See Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S.Ct. 1384, 1387, 134 L.Ed.2d 577 (1996). The words of a claim "are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005), *cert. denied*, 126 S.Ct. 1332 (2006), *quoting Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). Ordinary and customary meaning is "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention[.]" *Id.* at 1313. When the ordinary and customary meaning of a term is not readily apparent, "the court looks to 'those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean.'" *Id.* at 1314, *quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004). Those sources include the words of the claims themselves, the patent specification, the prosecution history, and extrinsic evidence. *Id.*; *see also Vitronics*, 90 F.3d at 1582.

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[1] Plaintiff also sues defendants for false advertising under the Lanham Act, 15 U.S.C. § 1125(a). (*See* Plf. Sec. Am. Compl. at 6-7, ¶¶ 42-47). That cause of action is not affected by the court's claim construction ruling.

The ordinary meaning of a claim term cannot be determined in a vacuum. *Phillips*, 415 F.3d at 1315; *see also Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). Rather, patent claims "must be read in view of the specification, of which they are a part." *Phillips,* 415 F.3d at 1315, *quoting Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995), *aff'd*, 116 S.Ct. 1384 (1996). The specification is always highly relevant to the claim construction analysis and, thus, is the primary basis for construing the claims. *Id.* The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication. *Vitronics*, 90 F.3d at 1582. The court may also consider the prosecution history in determining the meaning of disputed claim terms. *Id.* at 1582-83; *see also CVI/Beta Ventures, Inc. v. Tura LP.*, 112 F.3d 1146, 1158 (Fed. Cir. 1997), *cert. denied*, 118 S.Ct. 1039 (1998). The prosecution history contains a complete record of all proceedings before the Patent and Trademark Office ("PTO"), including any express representations made by the applicant regarding the scope of the claims. *Vitronics,* 90 F.3d at 1582. Because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and may be less useful for claim construction purposes. Nonetheless, "the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips,* 415 F.3d at 1317, *citing Vitronics*, 90 F.3d at 1582-83.

While most patent claims can be construed solely on the basis of intrinsic evidence, extrinsic evidence may be considered "for background and education on the technology implicated by the presented claim construction issues." *Key Pharmaceuticals v. Hercon Laboratories Corp.*, 161 F.3d 709, 716 (Fed. Cir. 1998). Extrinsic evidence consists of all evidence external to the patent and the

prosecution history, including expert and inventor testimony, dictionaries, and learned treatises. *Markman*, 52 F.3d at 980; *see also Vitronics*, 90 F.3d at 1583. Although extrinsic evidence is generally less reliable and less probative than intrinsic evidence, it may assist the court in better understanding the underlying technology and the way in which one skilled in the art might use the claim terms. *Phillips,* 415 F.3d at 1318. However, the court must discount any extrinsic evidence "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id.*, *quoting Key Pharmaceuticals*, 161 F.3d at 716.

III.

The patents-in-suit describe combinations of various saccharides used as dietary supplements. (*See* Plf. Cl. Constr. App. at 4-19, 20-35, 36-51, 52-68). Specifically, Claim 1 of the '807 Patent claims:

> A dietary supplement composition, comprising: *nutritionally effective amounts* of *isolated and purified* galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose.

(*Id.* at 18, col. 18, ll. 28-32) (emphasis added). Claim 1 of the '431 Patent claims:

> A dietary supplement composition comprising: a *nutritionally effective amount* of *isolated and purified* acetylated mannose; and a *nutritionally effective amount* of at least five *isolated and purified saccharides* selected from: galactose, glucose, mannose, xylose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, iduronic acid and arabinogalactan.

(*Id.* at 34, col. 20, ll. 47-55) (emphasis added). Claim 1 of the '064 Patent claims:

> A dietary supplement composition comprising a *nutritionally effective amount* of *isolated and purified* acetylated mannose; and further comprising [a] nutritionally effective amount of at least five

> saccharides essential for humans, comprising: gum ghatti; glucosamine; tragacanth gum; and a source of glucose.

(*Id.* at 50, col. 18, ll. 54-64) (emphasis added). Claim 1 of the '220 Patent claims:

> A dietary supplement composition, comprising: a *nutritionally effective amount* of *isolated and purified* acetylated mannose; and a nutritionally effective amount of at least five *saccharides* selected from: galactose, glucose, mannose, xylose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine, arabinose, glucuronic acid, galacturonic acid, glucosamine, galactosamine, rhamnose, iduronic acid and arabinogalactan.

(*Id.* at 67-68, col. 20, ll. 62-67 & col. 21, ll. 1-3) (emphasis added). In their claim construction briefs, the parties seek construction of the terms "isolated and purified," "saccharides," and "nutritionally effective amount." Their fundamental disagreement is whether each saccharide identified in Claim 1 of the patents must be individually separated from other saccharides before the ingredients are combined to make a dietary supplement composition, or whether the isolated and purified saccharides claimed by the patents may exist in combination with other saccharides as they appear in nature.[2]

A.

As a preliminary matter, both parties move to strike the testimony of each other's experts on the ground that reliance on such evidence is contrary to the hierarchy of analysis established in *Phillips*. (*See* Def. Mot. to Clarify at 3; Plf. Mot. to Strike at 4). The court has not relied on any expert testimony or other extrinsic evidence in construing the disputed claim terms. Consequently, the motions to strike are denied as moot. *See Mannatech v. Glycobiotics Int'l, Inc.*, 513 F.Supp.2d

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[2] Claim 1 is the sole independent claim of the '807, '431, '064, and '220 Patents. The parties seek the same construction of the disputed claim terms where those terms appear either explicitly or by reference in the dependent claims of the patents-in-suit. *See Forest Laboratories, Inc. v. Abbott Laboratories*, 239 F.3d 1305, 1310 (Fed. Cir. 2001) ("We [ ] construe independent claims consistently with the claims that depend from them."). Also, because the patents all derive from the same parent application and share many common terms, the court must interpret the claims consistently across all asserted patents. *See NTP, Inc. v. Research In Motion, Ltd.*, 418 F.3d 1282, 1293 (Fed. Cir. 2005).

754, 762 n.5 (N.D. Tex. 2007) ("*Mannatech I*") (overruling as moot objections to expert testimony where such testimony was not considered by the court in making claim construction ruling).[3]

Plaintiff also objects to the identification by defendants of "[a]ll prior art cited during the prosecution of the asserted patents" to support their proposed claim construction. (*See* Plf. Mot. to Strike at 4). According to plaintiff, allowing defendants to identify broad categories, rather than specific documents, is prejudicial and defeats the purpose of requiring the parties to prepare a Joint Claim Construction Statement. However, plaintiff does not explain, much less prove, how it has been prejudiced by the broad designation of prior art. Unless plaintiff can demonstrate prejudice, there is no reason to exclude from the claim construction analysis any prior art cited by the parties during the prosecution of the patents-in-suit. Plaintiff's objection is overruled.

B.

The first disputed claim term is "isolated and purified." Plaintiff asks the court to construe the term simply to mean "separated from other, unwanted substances." (*See* Plf. Cl. Constr. Br. at 17). While defendants agree that the "isolation" and "purification" of a substance at least requires separation from unwanted substances, they interpret the claim term to mean that each saccharide identified in the patent must be individually separated from the other saccharides in the patent. (*See* Def. Cl. Constr. Br. at 3, 9). Defendants further argue that the terms "isolated" and "purified" are not synonymous, and that the term "purified" requires each saccharide to be "further refined to a desired level of concentration." (*Id.* at 21). Thus, defendants ask the court to construe "isolated and purified" to mean "individually separated from other, unwanted substances from a source by a process that achieves a desired level of concentration of each saccharide." (*Id.* at 18).

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[3] Because the court has not considered any expert testimony, defendants' motion to clarify the *Markman* procedure and for an order prohibiting the deposition of their rebuttal expert is also moot.

1.

The court initially observes that nothing in the language of the patent claims or the specification suggests that each saccharide must be individually separated from the other saccharides. In support of their proposed claim construction, defendants point to Claim 10 of the '807 Patent, which provides that:

> [the] said galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose [of Claim 1] are *isolated and purified from* predigested gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, aloe vera extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, acetylated polymannose, maltose, glucan, lentinan, mannan, levan, hemicellulose, inulin, fructan or lactose.

(Plf. Cl. Constr. App. at 19, col. 19, ll. 1-11 & col. 10, ll. 1-2). However, this language limits only the *source* of the saccharides. It does not require that each saccharide be individually separated from every other saccharide in the source. Nor does it prevent several of the saccharides from being "isolated and purified" together, apart from other unwanted substances present in the natural source.

Similarly, Claim 8 of the '431 Patent requires that:

> at least five isolated and purified saccharides are obtained from the group consisting of gum tragacanth, guar gum, grain flour, rice flour, sugar cane, beet sugar, potato, milk, agar, algin, locust bean gum, psyllium, karaya gum, seed gums, Larch tree extract, gum ghatti, starch, cellulose, degraded cellulose, fructose, high fructose corn syrup, pectin, chitin, acacia, gum arabic, alginic acid, carrageenan, dextran, xanthan gum, chondroitin sulfate, sucrose, maltose, glucan, lentinan, mannan, levan, hemi-cellulose, inulin, fructan, and lactose.

(*Id.* at 35, col. 21, ll. 1-13 & col. 22, ll. 1-6). Again, this limitation merely identifies natural *sources* of the claimed saccharides. Claim 1 does not mention possible sources of the saccharides listed in

the patent. Thus, contrary to defendants' argument, Claim 1 and Claim 8 are not superfluous. (*See* Def. Cl. Constr. Br. at 13).

In addition, the patent specification plainly states that the saccharides comprising the dietary supplement composition may be present "in monomeric, oligomeric or polymeric and derivatized or underivatized form." (Plf. Cl. Constr. App. at 12, col. 5, ll. 45-46). The specification explains that "the saccharides can be in the form of mono-, oligo- and/or polysaccharides, e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose." (*Id.* at 13, col. 8, ll. 42-46). This language directly contradicts defendants' argument that the saccharides must be obtained alone.

2.

Defendants also rely on Example 2 in the specification of the '807 Patent to support their proposed construction of "isolated and purified." Example 2 reads:

> Another suitable composition for a product according to the present invention is as follows:
>
> 25 kilograms each of galactose, glucose, mannose, N-acetylneuraminic acid, fucose, N-acetylgalactosamine, N-acetylglucosamine and xylose *available from* Florida Food Products as well as *Aldrich Chemical Company and Sigma Chemical* is charged into a stainless steel ribbon blender and mixed for five (5) minutes. Then 250 grams of Aerosil 380 (silica gel) is added to the mixture as a flowing agent and 200 kilograms of rice flour, a source of glucose, is added as a gluten-free filler. The mixture is then agitated for fifteen (15) minutes. Finally, 100 grams of calcium stearate is added to the mixture as a lubricant and the mixture is agitated for an additional three (3) minutes to generate a bulk powder. the powder is then encapsulated into size # 1 gelatin capsules at a fill weight of 250 mg using a Model 8 (Elanco) capsule filling machine.

(Plf. Cl. Constr. App. at 15, col. 12, ll. 30-46) (emphasis added). According to defendants, the term "isolated and purified" was added late in the prosecution of the '807 Patent after numerous rejections

by the patent examiner in light of the prior art. (*See* Def. Cl. Constr. App., Exh. J). When challenged by the examiner to show support, by way of specific examples in the specification, "of the concept of a dietary supplement composition comprising a nutritionally effective amount of isolated and purified saccharides," counsel for the applicants cited to Example 2. (*Id.*, Exh. K at 6). Because no other specific examples of "isolated and purified" saccharides were mentioned in response to the examiner's inquiry, defendants maintain that the applicants surrendered all other embodiments and that the invention claimed by the patent is limited to that described in Example 2. (Def. Cl. Constr. Reply Br. at 3-4).

This argument is virtually identical to the one rejected by the court in *Mannatech I.* In that case, which was decided by the undersigned magistrate judge with the consent of the parties, plaintiff alleged that a dietary supplement manufactured and sold by the defendant infringed one or more claims of the '807 and '431 Patents. The defendant argued, *inter alia*, that the term "isolated and purified" meant "obtained alone with other components removed therefrom." *Mannatech I*, 513 F.Supp.2d at 758. In support of its proposed claim construction, the defendant relied heavily on Example 2 of the '807 Patent. *See id.* at 758-59. The court rejected this selective reading of the claim language and refused to limit the claim to the specific embodiment disclosed in Example 2. As the court explained:

> The Federal Circuit has cautioned against such an approach to claim construction, "even when a specification describes very specific embodiments of the invention or even describes only a single embodiment, unless the specification makes clear that 'the patentee . . . intends for the claims and the embodiments in the specification to be strictly coextensive.'" *JVW Enterprises, Inc. v. Interact Accessories, Inc.*, 424 F.3d 1324, 1335 (Fed. Cir. 2005), *quoting Phillips*, 415 F.3d at 1323. Here, the patent specification makes clear that the invention includes sugars available from a wide variety of natural and synthetic sources, and that "the composition of the

> invention is not intended to be limited by the source from which the [sugars] are obtained."

Id. at 759. Based on the intrinsic evidence, including the specification and the prosecution history of the '807 Patent, the court construed the term "isolated and purified" to mean "separated from other, unwanted substances." *Id.* at 762.[4]

Like *Mannatech I*, there is no evidence in this case that the applicant intended for the claims and the embodiments in the specification "to be strictly co-extensive." To the contrary, the patent specification provides examples of several preferred embodiments and expressly states:

> The carbohydrates included in the dietary supplement of the invention are available from a wide variety of natural and synthetic sources such as shrubs, trees, plants, yeasts, fungi, molds, gums, resins, starch and cellulose derivatives and natural mucin sources. Specifically, some of the natural sources include: (a) shrub or tree exudates which contain acacia, karaya, tragacanth, or ghatti; (b) marine guns which include agar, algin, or carrageenan; (c) seed gums which include guar, locust bean, or psyllium; (d) plant extracts which contain pectins or acetylated polymannose; (e) starch and cellulose derivatives such as hetastarch, carboxymethylcellulose, ethylcellulose, hydroxypropyl methylcellulose, methylcellulose, oxidized cellulose; and microbial gums which contain dextrans, xanthan.

(Plf. Cl. Constr. App. at 13, col. 7, ll. 48-62; *see also id.* at 12, col. 5, 63-67 & col. 6, ll 1-7). Moreover, under the doctrine of prosecution disclaimer, a patentee may limit the meaning of a claim term only "by making a clear and unmistakable disavowal of scope during prosecution." *Purdue Pharma L.P. v. Endo Pharmaceuticals Inc.*, 438 F.3d 1123, 1136 (Fed. Cir. 2006); *see also Seachange Int'l, Inc. v. C-COR Inc.*, 413 F.3d 1361, 1372-73 (Fed. Cir. 2005). Here, the prosecution history fails to indicate that the applicant "clearly and unmistakably" gave up embodiments made

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[4] Although the court is not bound by a claim construction ruling in a prior suit, it may look to the ruling for guidance. *See, e.g. Rambus, Inc. v. Hynix Semiconductor, Inc.*, 569 F.Supp.2d 946, 967 (N.D. Cal. 2008); *In re Omeprazole Patent Litigation*, 490 F.Supp.2d 381, 419 (S.D.N.Y. 2007), *aff'd*, 281 Fed.Appx. 974, 2008 WL 2369864 (Fed. Cir. Jun. 10, 2008), *citing Burke, Inc. v. Bruno Independent Living Aids, Inc.*, 183 F.3d 1334, 1338 (Fed. Cir. 1999).

using gums, extracts, and other sources that naturally include more than one saccharide. As counsel for the applicant told the patent examiner:

> [T]he present application includes *an example* directed to a composition of individual sugars. Specifically, please see Example 2 which is directed to a composition that includes 25 kilograms each of galactose, glucose, mannose, N-acetyleuraminic acid, fucose, N-acetylgalactosamine, N-acetylyglucosamine and xylose which would have to be isolated and purified at some point.

(Def. Cl. Constr. App., Exh. K at 6) (emphasis added). Nothing in this response unambiguously disclaims dietary supplement compositions comprised of saccharides drawn from sources other than those described in Example 2. The response merely provides "an example directed to a composition of individual sugars," without suggesting that it is the *only* example. There is no evidence that the applicant intended to disavow all the other examples or embodiments set forth in the specification in order to gain approval for the patent.

3.

Defendants further argue that plaintiff's proposed construction of "isolated and purified," which is the same construction given to the term by the court in *Mannatech I*, fails to give independent meaning to the term "purified." (*See* Def. Cl. Constr. Br. at 19). It is true that use of two terms in close proximity in the same claim gives rise to an inference that a different meaning should be assigned to each term. *See Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 93 F.3d 1572, 1579 (Fed. Cir. 1996). However, that inference is not conclusive. "[I]t is not unknown for different words to be used to express similar concepts, even though it may be poor drafting practice." *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1373 (Fed. Cir. 2004). Such is the case here. There is nothing in the claim language, the specification, or the prosecution history of the patents-in-suit to suggest that the saccharides must be refined to any particular level of

concentration. *See Mannatech I*, 513 F.Supp.2d at 762 (expressly rejecting argument that "isolated and purified" saccharides were required to be at least 95% pure). Accordingly, the court should follow *Mannatech I* and construe the term "isolated and purified" to mean "separated from other, unwanted substances."

C.

Next, the parties seek construction of the term "saccharides" as used in Claim 1 of the '431 Patent and Claim 1 of the '220 Patent. The parties agree that the term, which is defined in the specification, should be construed to at least mean "carbohydrates or sugars which can be in the form of mono-, oligo-, and/or polysaccharides." (*See* Plf. Cl. Constr. App. at 28, col. 8, ll. 63-64; *see also id.* at 61, col. 8, ll. 63-64). However, plaintiff argues that the phrase "*e.g.* a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose" -- which also appears in the specification -- should be part of the definition. (Plf. Cl. Constr. Br. at 16). Defendants oppose expanding the definition to include the additional language proposed by plaintiff.

The argument made by plaintiff is based on the recent decision in *Sinorgchem Co. Shandong v. Int'l Trade Commission*, 511 F.3d 1132 (Fed. Cir. 2007). In *Sinorgchem*, the Federal Circuit construed the term "controlled amount" used in two patents claiming a method of producing the chemical compounds 6PPD and 4-ADPA. The specification included the following language:

> A "controlled amount" of protic material is an amount up to that which inhibits the reaction of aniline with nitrobenzene, *e.g.* up to about 4% H_2O based on the volume of the reaction mixture when aniline is used as a solvent.

Sinorgchem, 511 F.3d at 1136. Although the term "controlled amount" was defined in the specification, the parties disagreed as to whether the language "*e.g.* up to about 4% H_2O based on

the volume of the reaction mixture when aniline is used as a solvent" should be included as part of the definition. *Id.* at 1137. The Federal Circuit construed the term to include the disputed language because "the drafter clearly, deliberately, and precisely defined the term 'controlled amount' of protic material as 'an amount up to that which inhibits the reaction of aniline with nitrobenzene, e.g., up to about 4% H_2O based on the volume of the reaction mixture when aniline is utilized as the solvent.'" *Id.* at 1136.

By contrast, the specification in the '431 Patent and the '220 Patent does not define "saccharide" to expressly include the phrase "*e.g.* a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose." Rather, the specification reads:

> As used herein, the term "carbohydrate" is used interchangeably with the terms "saccharide", "polysaccharide", "oligosaccharide" and "sugar" the definitions of which are well known in the art of carbohydrate chemistry. Although the compositions of the invention are intended to include at least one of the eleven essential saccharides, it should be noted that the saccharides can be in the form of mono-, oligo-, and/or polysaccharides, e.g. a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose. Therefore, by controlling the amount of particular gums in a given dietary supplement, one can control the amount of the respective saccharides in said dietary supplement.

(Plf. Cl. Constr. App. at 28-29, col. 8, ll. 57-67 & col. 9, ll. 1-3; *see also id.* at 61-62, col. 8, ll. 57-67 & col. 9, ll. 1-3). The definition states that, for purposes of the claimed invention, the term "saccharide" means the same thing as "carbohydrate," "polysaccharide," "oligosaccharide," and "sugar." (*Id.* at 28, col. 8, ll. 57-59; *see also id.* at 61, col. 8, ll. 57-59). *See Sinorgchem*, 511 F.3d at 1136, *citing Cultor Corp. v. A.E. Staley Manufacturing Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) (where a term in the specification is set off by quotation marks, it is often a strong indication that

what follows is a definition). The sentence that follows reiterates that a saccharide can be in the form of monosaccharide, an oligosaccharide, or a polysaccharide. (Plf. Cl. Constr. App. at 28, col. 8, ll. 63-64; *see also id.* at 61, col. 8, ll. 63-64). The same sentence elaborates, by way of example, that a composition containing gum tragacanth and guar gum will be considered as containing seven specific saccharides. (*Id.* at 28, col. 8, ll. 64-67; *see also id.* at 61, col. 8, ll. 64-67). This example is repeated throughout the specification. (*See id.* at 28-30, col. 8, ll. 19-22 & 26-46, col. 12, ll. 34-50; *see also id.* at 61-63, col. 8, ll. 19-22 & 26-46, col. 12, ll. 34-50).

When read in the context of the specification as a whole, it is clear that the language plaintiff seeks to incorporate into the definition of "saccharide" is not part of the definition. Rather, the language "*e.g.* a composition containing gum tragacanth and guar gum will be considered as containing galacturonic acid, fucose, xylose, arabinose, rhamnose, mannose and galactose" is an example directed to a preferred embodiment. Generally, particular embodiments and examples appearing in the specification will not be read into the claims. *See Texas Instruments, Inc. v. United States Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986). Thus, the court should construe the term "saccharides" to mean "carbohydrates or sugars which can be in the form of mono-, oligo-, and/or polysaccharides."

D.

Finally, both parties seek construction of the phrase "nutritionally effective amount" as used in Claim 1 of the patents-in-suit. Plaintiff argues that the phrase should be construed to mean "that amount which will provide a beneficial nutritional effect or response in a mammal," which is the definition found in the specification. (*See* Plf. Cl. Constr. Br. at 14-15). While acknowledging that "nutritionally effective amount" is defined in the specification, defendants maintain that the definition is "circular" and urge the court to hold the phrase invalid for indefiniteness. (*See* Def. Cl.

Constr. Br. at 22-23). Alternatively, defendants propose that the phrase be construed to mean a "sufficient amount of each saccharide to cause a beneficial response as measured by a statistically significant improvement in a marker." (*Id.* at 24).

The court declines to entertain defendants' invalidity argument at the claim construction stage. *See Intervet America, Inc. v. Kee-Vet Laboratories, Inc.*, 887 F.2d 1050, 1053 (Fed. Cir. 1989) ("Ambiguity, undue breadth, vagueness, and triviality are matters which go to claim *validity* . . ., not to interpretation or construction.") (emphasis in original). Although a determination of indefiniteness is intertwined to some degree with claim construction, a court must first attempt to determine what a claim means before it can determine whether the claim is invalid for indefiniteness. *See Harrah's Entertainment v. Station Casinos, Inc.*, 321 F.Supp.2d 1173, 1176 (D. Nev. 2004), *aff'd*, 154 Fed.Appx. 928, 2005 WL 3086716 (Fed. Cir. Nov. 15, 2005). Whether the patents-in-suit are invalid because the definition of "nutritionally effective amount" fails to provide one skilled in the art with any objective standards for determining what amount of a saccharide would be "nutritionally effective" is a matter more appropriately addressed on summary judgment. *See Nisus Corp. v. Perma-Chink Systems, Inc.*, No. 3:03-CV-120, 2005 WL 5164855 at *8 (E.D. Tenn. Jan. 25, 2005) (declining to consider issue of indefiniteness at claim construction phase); *Pharmastem Therapeutics, Inc. v. Viacell, Inc.*, No. 02-148 GMS, 2003 WL 124149 at *1, n.1 (D. Del. Jan. 13, 2003) (same); *ASM America, Inc. v. Genus, Inc.*, No. C-01-2190-EDL, 2002 WL 1892200 at *15 (N.D. Cal. Aug. 15, 2002) (same).[5]

Where the specification explains and defines a claim term, without ambiguity or incompleteness, there is no need to search further for the meaning of the term. *See Sinorgchem*, 511

[5] Defendants have filed a motion for partial summary judgment on the issue of indefiniteness. (*See* Doc. #87). That motion has been fully briefed and is pending before the district judge.

F.3d at 1138; *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1478 (Fed. Cir. 1998). In this case, the specification expressly defines "nutritionally effective amount" as "that amount which will provide a beneficial nutritional effect or response in a mammal." (*See, e.g.* Plf. Cl. Constr. App. at 14, col. 9, ll. 66-67 & col. 10, l. 1). The specification goes on to explain that the precise amount of a saccharide that is "nutritionally effective" will vary from mammal to mammal depending on the substance involved. (*See, e.g. id.*, col. 10, ll. 1-9). There is no ambiguity or incompleteness in this definition. Indeed, the Federal Circuit has concluded that the phrase "effective amount" is a common and unambiguous claim term. *See Geneva Pharmacueticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373, 1383 (Fed. Cir. 2003) (finding that "effective amount" is a common and generally acceptable term for pharmaceutical claims and is not ambiguous or indefinite); *Nisus Corp.*, 2005 WL 5164855 at *7-8) (applying *Geneva Pharmacueticals* in non-pharmaceutical context); *Kao Corp. v. Unilever U.S., Inc.*, 334 F.Supp.2d 527, 551-52 (D. Del. 2004), *aff'd*, 441 F.3d 963 (Fed. Cir. 2006) (same). Therefore, the court need not look any further than the express language of the specification for the definition of the disputed phrase. "Nutritionally effective amount" should be construed to mean "that amount which will provide a beneficial nutritional effect or response in a mammal."

RECOMMENDATION

The court should construe the disputed terms and phrases used in the '807 Patent, the '431 Patent, the '064 Patent, and the '220 Patent as follows:

(a) the term "isolated and purified" means "separated from other, unwanted substances;"

(b) the term "saccharides" means "carbohydrates or sugars which can be in the form of mono-, oligo-, and/or polysaccharides;" and

(c) the phrase "nutritionally effective amount" means "that amount which will provide a beneficial nutritional effect or response in a mammal."

A copy of this report and recommendation shall be served on all parties in the manner provided by law. Any party who objects to any part of this report and recommendation must file specific written objections within 10 days after being served with a copy. *See* 28 U.S.C. § 636(b)(1); FED. R. CIV. P. 72(b). In order to be specific, an objection must identify the specific finding or recommendation to which objection is made, state the basis for the objection, and specify the place in the magistrate judge's report and recommendation where the disputed determination is found. An objection that merely incorporates by reference or refers to the briefing before the magistrate judge is not specific. Failure to file specific written objections will bar the aggrieved party from appealing the factual findings and legal conclusions of the magistrate judge that are accepted or adopted by the district court, except upon grounds of plain error. *See Douglass v. United Services Automobile Ass'n*, 79 F.3d 1415, 1417 (5th Cir. 1996).

DATED: August 28, 2009.

JEFF KAPLAN
UNITED STATES MAGISTRATE JUDGE